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KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
BURGESS, JOSEPH D	

ART UNIT	PAPER NUMBER
3626	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/824,130	FORTH ET AL.	
	Examiner	Art Unit	
	JOSEPH BURGESS	3626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to an amendment filed on 07/31/2009. Claims 1, 11, 17, 24, and 31 have been amended. Therefore, claims 1-32 are currently pending and have been examined.

Response to Amendments

1. Applicant's amendments to claims are herein acknowledged. In response to the amendment to claims 1, 11, 17, 24, and 31, the Examiner has entered a rejection under § 103, where the Examiner has applied art already of record. Further, the Examiner has entered rejections under § 101 and § 112, second paragraph as a result of the amendment.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 11-16 and rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 11 recites "reading, from a computer memory, the unique authentication code at said destination site". It is unclear from this amendment to the claim and the wording of the other steps of this method whether the package is even shipped because the code can be read from a computer memory at the destination site without reading it from a package at the destination site. All claims dependent on this claim are rejected for the same reasons.

5. Claim 24 recites "reading, from a computer memory, the authentication code from the product packaging at the origin location prior to distribution". It is unclear from the wording of this amendment to the claim if the code is read from the product packaging or from computer memory. For examination purposes, Examiner will interpret the code as being read from product packaging. All claims dependent on this claim are rejected for the same reasons.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 11-16 and 24-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

8. Claims 11-16 and 24-32 are directed to a method. Based on Supreme Court precedent and recent Federal Circuit decisions, the Office's guidance to an examiner is that a § 101 process must (1) be tied to a particular machine or apparatus or (2) transform underlying subject matter (such as an article or materials) to a different state or thing. *In re Bilski et al*, 88 USPQ 2d 1385 CAFC (2008); *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).

9. To qualify as a § 101 statutory process, the claim should recite the particular machine or apparatus to which it is tied, for example by identifying the machine or apparatus that accomplishes the method steps, or positively reciting the subject matter that is being

transformed, for example by identifying the material that is being changed to a different state.

10. There are two corollaries to the machine-or-transformation test. First, a mere field-of-use limitation is generally insufficient to render an otherwise ineligible method claim patent-eligible. This means the machine or transformation must impose meaningful limits on the method claim's scope to pass the test. Second, insignificant extra-solution activity will not transform an unpatentable principle into a patentable process. This means reciting a specific machine or a particular transformation of a specific article in an insignificant step, such as data gathering or outputting, is not sufficient to pass the test.

11. Here, applicant's method steps fail the first prong of the new test because they are not tied to a particular machine. For example, claim 11 recites "wherein the method is performed by one or more computing devices", which makes it unclear if one or more than one computing device is involved with each and every step or just one or some of the steps. Because it can be construed that the one or more than one computing device may be directed to insignificant extra solution activity such as data storage and the like, this limitation inserted into the claim is insufficient to render the total of the method steps as statutory.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. Claims 1-17, 21, and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael, et al. (US 2003/0088442 A1) in view of Cunningham (US 6,859,780 B1) in further view of Moore (US 6,456,729 B1).

14. **Claim 1:**

Michael, as shown, discloses the following limitation:

- *an activation computer configured to store authentication codes in a database and associate said authentication codes with pharmaceutical packages* (see at least paragraphs 0022-0023 and 0076, i.e. automatic identification codes or barcodes are associated with drug samples and are stored in a main inventory database),

Michael does not disclose the following limitation, but Cunningham as shown does:

- *wherein said activation computer is further configured to activate said authentication codes for pharmaceutical packages that are being sent to destination sites* (see at least column 3, lines 10-34, i.e. pharmaceutical trial media is activated by the central computing station to validate that prescription will be available at pharmacy destination);
- wherein the authentication computer is configured to flag said activated authentication code as expired in response to a successful verification of said authentication code (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which expire once the validations are exhausted or the product media are unique for each pharmaceutical used and would expire with the prescription of each unique product).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code activation technique of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *an authentication computer configured to receive authentication codes that are read from pharmaceutical packages received at said destination sites and determine whether said authentication codes have been activated* (see at least column 6, lines 8-36, i.e. a field reader identifies the codes on marked packages that have been shipped to a field destination and then validates the codes).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the code validation technique of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

The Examiner notes that, while the combination of Michael/Cunningham/Moore discloses the limitations above, the limitations are drawn to non-functional descriptive material and are not functionally involved with the system. The recited system would perform the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack,* 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)*; In re Lowry,* 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994)*; In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). See also MPEP 2106.

15. Claim 2:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said activation computer is configured to store additional information for said pharmaceutical packages in said database along with said activated authentication code* (see at least paragraph 0078, i.e. barcodes issued from manufacturer's location and attached to each drug sample provide information relating to that sample such as product type, lot number, expiration date, etc).

16. Claim 3:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *the authentication computer is configured to determine whether information received in connection with an authentication code corresponds to the additional information stored at said database* (see at least paragraphs 0076-0080, i.e. barcodes that include additional information about a drug sample are read by scanner at destination and this information is validated by main inventory database during synchronization process).

17. Claim 4:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said additional information includes at least one of: pharmaceutical package destination information, pharmaceutical type, pharmaceutical quantity, pharmaceutical dosage, or pharmaceutical manufacturer information* (see at least paragraph 0078, i.e. barcodes issued from manufacturer's location and attached to each drug sample provide information relating to that sample such as product type, lot number, expiration date, etc).

18. Claim 5:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *the authentication code is a machine readable code* (see at least paragraph 0078, i.e. barcode can be read by barcode reader).

19. Claim 6:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Moore discloses the limitation of *said authentication computer is configured to receive authentication codes from a code reader* (see at least column 6, lines 8-36, i.e. host computer receives data from field reader). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the code reader of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

20. Claim 7:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *a server in communication with said database, said activation computer, and said authentication computer, wherein said server transmits an activated authentication code to said*

authentication computer, and said authentication computer is configured to store the activated authentication code received from said server (see at least column 10, lines 27-49, i.e. prescriber terminal communicates identification codes to central computing station which stores these in its database). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code storage function of Cunningham because it allows for codes to be readily available to be verified when they are sent from the readers to the authentication computer which allows for more efficiency in tracking pharmaceutical products.

21. Claim 8:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *said additional information comprises the intended destination of said pharmaceutical packages* (see at least column 6, lines 16-25, i.e. encoded information includes a pharmacy location identifier). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the identification of the intended destination technique of Cunningham because it allows the authentication computer to determine if the product has reached its intended destination which makes the shipping process more secure.

22. Claim 9:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *the intended destination includes intermediate and final destination information* (see at least paragraph 0023, i.e. manufacturer ships drug samples to pharmaceutical representative who ships them to doctors and this is all tracked thru the automatic identification code that is marked on the samples).

23. Claim 10:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *said authentication computer is configured to notify said activation computer in response to determining that a received authentication code corresponding to a pharmaceutical package is not an activated authentication code* (see at least column 10, lines 13-26, i.e. prescriber terminal determines that the product media is not valid and is therefore not activated). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the non-activated code determination of Cunningham because it gives the authentication computer the opportunity to determine if drugs have been shipped inadvertently, to the wrong destination, or that there are counterfeit products in the supply chain thus creating a more secure overall pharmaceutical shipping environment.

24. Claim 11:

Michael, as shown, discloses the following limitations:

- *storing said authentication code and additional product distribution information to a database storage* (see at least paragraph 0078, i.e. pharmaceutical sample barcode is read by reader and product information as well as information relating to the same is logged into local database);
- *reading, from a computer memory, the unique authentication code at said destination site* (see at least paragraph 0076-0080, i.e. barcodes are read from local memory on PDA at destination site to main database during synchronization);
- *verifying the read authentication code and additional product distribution information with said database storage* (see at least paragraphs 0076-0080, i.e. read barcodes and additional information are synchronized back to main inventory database to verify information);

- *wherein the method is performed by one or more computing devices* (see at least figure 2).

Michael does not disclose the following limitations, but Cunningham as shown does:

- *activating said unique stored authentication code to indicate that said pharmaceutical package is being sent to a destination site* (see at least column 3, lines 10-34, i.e. pharmaceutical trial media is activated by the central computing station to validate that prescription will be available at pharmacy destination);
- *notifying said system server whether said verification was successful* (see at least column 10, lines 13-26, i.e. if product trial media is deemed authentic, then prescriber terminal displays that the product trial media is valid);
- *expiring said activated stored authentication code in response to a successful verification of said authentication code* (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which expire once the validations are exhausted or the product media are unique for each pharmaceutical used and would expire with the prescription of each unique product).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the unique code system of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *correlating a unique authentication code with a pharmaceutical product package and additional product distribution information* (see at least column 1, lines 16-31, i.e. packaged goods are issued a unique mark to help determine such information as the final point of destination and other information);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the unique authentication code of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

The Examiner notes that, while combination of Michael/Cunningham/Moore discloses the limitations above, the limitations are drawn to non-functional descriptive material and are not functionally involved with the method. The recited method steps would be performed the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack,* 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)*; In re Lowry,* 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994)*; In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). See also MPEP 2106.

25. Claim 12:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said additional product distribution information includes at least one of destination information for a pharmaceutical product, manufacturer information for said product, receiving location information, product type, or product quantity* (see at least paragraph 0078, i.e. barcodes issued from manufacturer's location and attached to each drug sample provide information relating to that sample such as product type, lot number, expiration date, etc).

26. Claim 13:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said additional product distribution information is stored in a computer at said destination site* (see at least paragraph 0078, i.e. barcodes that include additional information about a drug sample are read by scanner at destination and this information is stored logged into a local database).

27. Claim 14:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said additional information is input by a user* (see at least paragraphs 0078-0079, i.e. product's additional information can be manually input).

28. Claim 15:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael, as shown, discloses the following limitation:

- *sending an authentication request, said authentication code read from said product packaging and said additional product distribution information to a system server* (see at least paragraphs 0022-0023 and 0076-0080, i.e. barcode, including additional product information is scanned and stored in local destination database and then this information is sent to main inventory database),

Michael does not disclose the following limitation, but Cunningham as shown does:

- *determining, in response to said authentication request, whether said authentication code read from said product packaging was an activated authentication code, and notifying said system server of the result of said determination* (see at least column

10, lines 13-49, i.e. central computing station determines if product media is activated and notifies associated database that it is activated).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the activated code determination of Cunningham because it gives the authentication computer the opportunity to determine if drugs have been shipped inadvertently, to the wrong destination, or that there are counterfeit products in the supply chain thus creating a more secure overall supply chain.

29. Claim 16:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Moore discloses the limitation of *verifying the read authentication code and additional product distribution information with said database comprises sending encoded data to said database* (see at least column 7, lines 14-41, i.e. encoded data including the final point of distribution and unique manufacturer identifier are applied to packages, scanned, and compared to stored encoded input data entries in the mass storage device data). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the ability to send encoded product data a database of Moore because it, "...provides a method for controlling and enabling the authentication and tracking of consumer goods to reduce the amount of counterfeit goods and to reduce the shipping of authentic goods to unauthorized points of final distribution..." (Moore, column 7, lines 14-18).

30. Claim 17:

Michael, as shown, discloses the following limitation:

- *a first code reader configured to read authentication codes from product packaging* (see at least paragraph 0078, i.e. barcode reader scans barcode of pharmaceutical sample);
- wherein the activation module is configured to deactivate said active authentication code in response to a successful verification of said authentication code (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which are deactivated once the validations are exhausted or the product media are unique for each pharmaceutical used and would deactivate with the prescription of each unique product).

Michael does not disclose the following limitation, but Cunningham as shown does:

- *an activation module configured to receive an authentication code read by said first code reader from product packaging prior to distribution* (see at least column 10, lines 3-26, i.e. prescriber terminal receives product media coding from magnetic cards swiped into card reader), *and to transmit an activation request to the system server* (see at least column 10, lines 27-49, i.e. prescriber terminal transmits activation requests to central computing station), *wherein said activation request comprises the authentication code read by said first code reader* (see at least column 10, lines 27-49, i.e. product media information previously read into prescriber terminal is uploaded to central computing station), *wherein the system server stores the authentication code as an active authentication code in response to the activation request* (see at least column 10, lines 27-49, i.e. central computing station stores product media information in database after activation).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code activation technique of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *a system server including a first authentication module* (see at least column 6, lines 21-36, i.e. host computer uses database to validate code);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the system server of Moore because it allows for codes to be stored and authenticated by the manufacturer which provides for a more secure environment for the pharmaceutical supply chain.

The Examiner notes that, while the combination of Michael/Cunningham/Moore discloses the limitations above, the limitations are drawn to non-functional descriptive material and are not functionally involved with the system. The recited system would perform the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack,* 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry,* 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994); *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). See also MPEP 2106.

31. Claim 21:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said destination information includes intermediate destination information and final destination information* (see at least paragraph 0023, i.e. manufacturer ships drug samples to pharmaceutical representative who ships them to doctors and this is all tracked thru the automatic identification code that is marked on the samples).

32. Claim 23:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Moore discloses the limitation of *said activation module is further configured to encode said activation request, and to transmit said encoded activation module to said system server, and wherein said system server is configured to decode said encoded activation request* (see at least column 7, lines 14-41, i.e. packages are marked with unique activated code comprising encoded data which is also stored in a mass storage device, the code is then scanned which decodes the pattern and allows the system to compare the encoded data against stored encoded data entries in the mass storage device). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the encoding and decoding technique of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

33. Claim 24:

Michael, as shown, discloses the following limitation:

- *applying an authentication code to product packaging* (see at least paragraph 0023, i.e. sample is marked with automatic identification code);

- *wherein the method is performed by one or more computing devices* (see at least figure 2).

Michael does not disclose the following limitations, but Cunningham as shown does:

- *sending an activation request to a system server, wherein said activation request includes the read authentication code* (see at least column 10, lines 3-49, i.e. code is read from magnetic cards and this code is downloaded from prescriber terminal to central computing station to validate activation);
- *activating the read authentication code in response to the activation request, comprising storing the read authentication code as an active authentication code at the system server* (see at least column 10, lines 27-49, i.e. central computing station approves activation and stores code from activated product media in database).
- flagging said active authentication code as expired in response to a successful verification of said authentication code (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which are deactivated once the validations are exhausted or the product media are unique for each pharmaceutical used and would deactivate with the prescription of each unique product);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the technique of sending and storing activation codes of Cunningham because it makes sure the activation codes are available and secure when they are needed to verify packages are being shipped to their correct destinations.

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *reading, from a computer memory, the authentication code from the product packaging at the origin location prior to distribution* (see at least column 5, line 57 –

column 6, line 6, i.e. at the place of origin for the packaging markings, a CCD camera validates that marks are appropriately printed on products);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the technique of reading the authentication code at the origin location of Moore because it allows for codes to be read and stored in computer memory as they are marked on packaging at the origin location. This makes the shipping process more secure in that it allows for validation of the package location from origination to final location.

The Examiner notes that, while the combination of Michael/Cunningham/Moore discloses the limitations above, the limitations are drawn to non-functional descriptive material and are not functionally involved with the method. The recited method would be performed the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994); *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). See also MPEP 2106.

34. Claim 25:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael, as shown, discloses the following limitation:

- *reading an authentication code from product packaging received at a receiving location* (see at least paragraph 0023, i.e. automatic identification code from sample is read by scanning device when received from pharmaceutical company);

Michael does not disclose the following limitations, but Cunningham as shown does:

- *sending the active authentication code to a product receiving location* (see at least column 10, lines 27-49, i.e. central computing station approves activation and sends specific approval code to prescriber terminal);

- *determining whether said authentication code read at said receiving location corresponds to said active authentication code* (see at least column 10, lines 27-49, i.e. central computing station determines if code downloaded from prescriber terminal is activated);
- *notifying a user of the result of said determination* (see at least column 10, lines 27-49, i.e. central computing station notifies prescriber terminal that activation is approved).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code activation technique of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

35. Claim 26:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael, as shown, discloses the following limitation:

- *sending a verification request and said authentication code read at said receiving location to said system server* (see at least paragraphs 0022-0023 and 0076-0080, i.e. barcode, including additional product information is scanned and stored in local destination database and then this information is sent to main inventory database),

Michael does not disclose the following limitations, but Cunningham as shown does:

- *determining whether said authentication code read at said receiving location corresponds to an active authentication code stored at said system server* (see at least column 10, lines 13-49, i.e. central computing station determines if product media is activated and notifies associated database that it is activated),
- *notifying the receiving location as to whether the authentication code read from product packaging at the receiving location corresponds to an active authentication*

code stored at the system server (see at least column 10, lines 27-49, i.e. central computing station notifies prescriber terminal that activation is approved).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the activated code determination and notification technique of Cunningham because it gives the authentication computer the opportunity to determine if drugs have been shipped inadvertently, to the wrong destination, or that there are counterfeit products in the supply chain thus creating a more secure overall supply chain.

36. Claim 27:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *expiring the active authentication code in response to determining that the authentication code read at the receiving location corresponds to the active authentication code* (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which expire once the validations are exhausted or the product media are unique for each pharmaceutical used and would expire with the prescription of each unique product), *wherein expiring comprises storing the active authentication code at the system server as an expired authentication code* (see at least column 11, line 61 – column 12, line 9, i.e. the central computing station stores a full record of all transactions including activations, validations and when pharmaceuticals have been expired and need to be replenished). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code expiring technique of Cunningham because it makes sure that the unique codes assigned to specific packages cannot be duplicated in the supply chain thus creating a more secure overall supply chain.

37. Claim 28:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *said activation request includes destination information for the product* (see at least column 6, lines 16-25, i.e. encoded information includes a pharmacy location identifier), *and wherein activating further comprises storing said destination information in connection with said active authentication code* (see at least column 10, lines 27-49, i.e. once product media is activated the central computing station stores the identity of the prescriber in the database). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the identification of the intended destination technique of Cunningham because it allows the authentication computer to determine if the product has reached its intended destination which makes the shipping process more secure.

38. Claim 29:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham, as shown, discloses the following limitation:

- *said activation request includes destination information for the product* (see at least column 6, lines 16-25, i.e. encoded information includes a pharmacy location identifier), *wherein activating further comprises storing said destination information in connection with said active authentication code at said system server* (see at least column 10, lines 27-49, i.e. once product media is activated the central computing station stores the identity of the prescriber in the database),

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the identification of the intended destination technique of Cunningham because it allows the authentication

computer to determine if the product has reached its intended destination which makes the shipping process more secure.

The combination of Michael/Cunningham does not disclose the following limitations, but Moore as shown does:

- *sending said destination information to a receiving location* (see at least column 11, lines 43-56, i.e. host computer sends message to field reader which displays pertinent information including destination),
- *determining whether receiving location information corresponds to said destination information from said system server* (see at least column 7, lines 34-41, i.e. encoded data is compared against data in mass storage device to determine if specified destination is correct),
- *notifying the receiving location as to whether the receiving location information corresponds to said destination information* (see at least column 11, lines 43-56, i.e. host computer sends message to field reader which displays pertinent information including destination and signals if package is counterfeit or has been received at wrong point of final distribution).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the destination determination and notification technique of Moore because it affords the system the opportunity to determine if drugs have been shipped inadvertently, to the wrong destination, or that there are counterfeit products in the supply chain thus creating a more secure overall supply chain.

39. Claim 30:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Moore discloses the limitation of *encoding said activation request, sending said encoded activation request to said system server, and decoding*

said encoded activation request at said server prior to said activating (see at least column 7, lines 14-41, i.e. packages are marked with unique activated code comprising encoded data which is also stored in a mass storage device, the code is then scanned which decodes the pattern and allows the system to compare the encoded data against stored encoded data entries in the mass storage device). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the encoding and decoding technique of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

40. Claim 31:

Michael, as shown, discloses the following limitation:

- *reading, from a computer memory, an authentication code from product packaging received at a receiving location* (see at least paragraph 0078, i.e. barcode on sample is read by reader when shipped to pharmaceutical representative)*;*
- *sending a verification request and said authentication code read at said receiving location to said system server* (see at least paragraphs 0022-0023 and 0076-0080, i.e. barcode, including additional product information is scanned and stored in local destination database and then this information is sent to main inventory database for verification)*;*
- wherein the method is performed by one or more computing devices (see at least figure 2).

Michael does not disclose the following limitations, but Cunningham as shown does:

- *sending an activation request, said read authentication code, and product destination information to a system server* (see at least column 6, lines 16-25 and 10, lines 27-49, i.e. destination and other encoded information is sent to central computing station to request activation of product media);
- *activating said read authentication code in response to said activation request, comprising storing said read authentication code as an active authentication code and said product destination information at said system server* (see at least column 6, lines 16-25 and 10, lines 27-49, i.e. product media including destination and other encoded information is activated by central computing station which stores this information in associated database);
- *verifying said authentication request, comprising comparing said authentication code read from product packaging at said receiving location to active stored authentication codes stored at the system server* (see at least column 10, lines 3-49, i.e. product media coding is read, validated by the prescriber terminal, the coding is uploaded to central computing station and activated once coding is compared to data in database);
- *notifying said receiving location whether said authentication request was verified, comprising indicating whether said authentication code read from product packaging at said receiving location corresponds to said active stored authentication code* (see at least column 10, lines 3-49, i.e. central computing station notifies prescriber of activation once data is compared in database);
- *expiring said active stored authentication code by storing said active authentication code at said system server as an expired authentication code* (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which expire once the validations are exhausted or the product media are unique for each pharmaceutical used and would expire with the prescription of each unique product).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code activation technique of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *reading an authentication code from a product packaging at said origin location prior to distribution* (see at least column 5, line 57 – column 6, line 6, i.e. at the place of origin for the packaging markings, a CCD camera validates that marks are appropriately printed on products)*;*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the technique of reading the authentication code at the origin location of Moore because it allows for codes to be read and stored in computer memory as they are marked on packaging at the origin location. This makes the shipping process more secure in that it allows for validation of the package location from origination to final location.

The Examiner notes that, while the combination of Michael/Cunningham/Moore discloses the limitations above, the limitations are drawn to non-functional descriptive material and are not functionally involved with the method. The recited method would be performed the same regardless of the specific data. Thus, this descriptive material will not distinguish the claimed invention from the prior art in terms of patentability, see *In re Gulack*, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983); *In re Lowry*, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994); *In re Ngai*, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). See also MPEP 2106.

41. Claim 32:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham, as shown, discloses the following limitation:

- *said activation request further comprises destination information* (see at least column 6, lines 16-25 and 10, lines 27-49, i.e. product media including destination and other encoded information is scanned at prescriber terminal which sends activation request to central computing station),

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the destination information of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitations, but Moore as shown does:

- *said method further comprises storing said destination information at said system server* (see at least column 8, lines 23-44, i.e. system allows for entering and storing a unique destination identifier into a CPU),
- *said verification request further comprises receiving location information* (see at least column 11, lines 43-56, i.e. host computer receives location information from field reader),
- *said verifying said authentication request further comprises comparing said receiving location information to said destination information* (see at least column 7, lines 14-41, i.e. method compares encoded data read from scanning to encoded data stored to mass storage device to determine if goods are authentic and if specified destination is correct),
- *said notifying said receiving location further comprises indicating whether said receiving location information corresponds to said destination information stored at said server* (see at least column 7, lines 14-41, i.e. method compares encoded data read from scanning to encoded data stored to mass storage device to determine if goods are authentic and if specified destination is correct).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the unique authentication code of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

42. Claims 18-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael, et al. (US 2003/0088442 A1) in view of Cunningham (US 6,859,780 B1) in further view of Moore (US 6,456,729 B1) in further view of **Admitted Prior Art**.

43. **Claim 18:**

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. The combination of Michael/Cunningham/Moore fails to explicitly disclose *at least a second code reader configured to read authentication codes from product packaging, and a second authentication module, configured to receive an authentication code read by said second code reader from product packaging and active authentication codes from said system server, and configured to determine whether said authentication code read by said second code reader corresponds to said active authentication code received from said system server, and to notify a user of said second code reader as to whether the authentication code read by said second code reader corresponds to said active authentication code.* However, it is **Admitted Prior Art** to have at least a second pharmaceutical tracking system in place when you already have a first one. For instance, in at least column 5, lines 41-56, Moore discloses that a system could comprise more than one computer or server, more than one marking system, more than one scanner or reader. Therefore, it would have been obvious to one of ordinary skill in the art to combine the drug inventory management system of Michael/Cunningham/Moore with the ability to have at least a second such system in place. The reason to combine a second drug inventory management system with the first would be because the manufacturer is shipping pharmaceuticals to multiple locations. Additionally, some of those multiple locations are just intermediate shipping points for the pharmaceutical products on their way to final destinations. This combination provides a predictable result because it is well known to have multiple tracking systems for authenticating multiple packages shipped to multiple destinations.

44. Claim 19:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. The combination of Michael/Cunningham/Moore fails to explicitly disclose *said second authentication module is further configured to transmit a verification request and said authentication code read by said second code reader to said system server, wherein said first authentication module is further configured to determine whether said authentication code received with said authentication request corresponds to an active authentication code stored at said system server, and wherein the first authentication module is configured to notify said second authentication module as to whether said authentication code received with said verification request corresponds to an active authentication code.* However, it is **Admitted Prior Art** to have at least a second pharmaceutical tracking system in place when you already have a first one. For instance, in at least column 5, lines 41-56, Moore discloses that a system could comprise more than one computer or server, more than one marking system, more than one scanner or reader. Therefore, it would have been obvious to one of ordinary skill in the art to combine the drug inventory management system of Michael/Cunningham/Moore with the ability to have at least a second such system in place. The reason to combine a second drug inventory management system with the first would be because the manufacturer is shipping pharmaceuticals to multiple locations. Additionally, some of those multiple locations are just intermediate shipping points for the pharmaceutical products on their way to final destinations. This combination provides a predictable result because it is well known to have multiple tracking systems for authenticating multiple packages shipped to multiple destinations.

45. Claim 20:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. The combination of Michael/Cunningham/Moore fails to explicitly

disclose *said activation request includes destination information for the product, said destination information is stored at the system server in connection with the active authentication code, said second authentication module is configured to receive said destination information from said system server with said active authentication code, and said second authentication module is further configured to determine whether information at said second code reader corresponds to said destination information received from said system server.* However, it is **Admitted Prior Art** to have at least a second pharmaceutical tracking system in place when you already have a first one. For instance, in at least column 5, lines 41-56, Moore discloses that a system could comprise more than one computer or server, more than one marking system, more than one scanner or reader. Therefore, it would have been obvious to one of ordinary skill in the art to combine the drug inventory management system of Michael/Cunningham/Moore with the ability to have at least a second such system in place. The reason to combine a second drug inventory management system with the first would be because the manufacturer is shipping pharmaceuticals to multiple locations. Additionally, some of those multiple locations are just intermediate shipping points for the pharmaceutical products on their way to final destinations. This combination provides a predictable result because it is well known to have multiple tracking systems for authenticating multiple packages shipped to multiple destinations.

46. Claim 22:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. The combination of Michael/Cunningham/Moore fails to explicitly disclose *said first authentication module is configured to store said previously active authentication code as an expired authentication code when said second authentication module determines that said authentication module read by said second code reader corresponds to said active authentication module.* However, it is **Admitted Prior Art** to have at least a second pharmaceutical tracking system in place when you already have a

first one. For instance, in at least column 5, lines 41-56, Moore discloses that a system could comprise more than one computer or server, more than one marking system, more than one scanner or reader. Therefore, it would have been obvious to one of ordinary skill in the art to combine the drug inventory management system of Michael/Cunningham/Moore with the ability to have at least a second such system in place. The reason to combine a second drug inventory management system with the first would be because the manufacturer is shipping pharmaceuticals to multiple locations. Additionally, some of those multiple locations are just intermediate shipping points for the pharmaceutical products on their way to final destinations. This combination provides a predictable result because it is well known to have multiple tracking systems for authenticating multiple packages shipped to multiple destinations.

Response to Arguments

47. Applicant's arguments regarding the 35 USC § 112, first paragraph rejections to claims 1-32 are sufficient to overcome the rejections set forth in the previous office action and, therefore this rejection is withdrawn.

48. Applicant's arguments regarding the 35 USC § 101 rejections to claims 11-16 and 24-32 have been considered put are not persuasive. The amendments made to claims 11, 24, and 31 that recite "wherein the method is performed by one or more computing devices" makes it unclear if one or more than one computing device is involved with each and every step or just one or some of the steps. The amendments also make it unclear if the one or more than one computing device is directed to insignificant extra solution activity such as data storage and the like and, therefore makes the amendments insufficient to render the total of the method steps as statutory.

49. Applicant's arguments the 35 USC § 103 rejections have been fully considered but they are not persuasive. In an effort to advance prosecution, Examiner has provided a response to applicant's arguments. Applicant argues:

i. Michael does not teach the concepts of tracking products from a source to a known destination and authenticating the product.

ii. Cunningham does not teach the concept of distributing pharmaceutical product with an authentication code.

iii. There is no motivation to combine Michael and Cunningham.

iv. Moore's code validation and applicant's code activation are different concepts.

v. Michael/Cunningham/Moore does not teach the concept of flagging a code as expired in response to successful verification of authentication code.

50. With regards to applicant's argument that Michael does not teach the concepts of tracking product from a source to a known destination and authenticating the product, Examiner respectfully disagrees. Michael, in at least figures 1-2, paragraphs 0023, and 0076-0082, discloses tracking pharmaceutical products from manufacturer (source) to a known destination (pharmaceutical representative/doctor). Further, it is noted that the features upon which applicant relies in the argument (i.e., a known destination) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, Michael, in at least paragraph 0078, discloses authenticating the pharmaceutical product by scanning in the barcode which contains information such as product type, lot number, and expiration date. Therefore, Michael provides for tracking products from a source to a known destination and authenticating the product.

51. With regards to applicant's argument that Cunningham does not teach the concept of distributing pharmaceutical product with an authentication code, Examiner respectfully disagrees. Cunningham, in at least abstract, figures 2-4A, column 3, lines 11-34, column 5, line 66 – column 6, line 6, and column 8, lines 5-24, discloses distributing a pharmaceutical product (product trial media) with an authentication code. Therefore, Cunningham provides for distributing pharmaceutical product with an authentication code.

52. Applicant argues that there is no motivation to combine the applied references. In response to Applicant's argument that there is no suggestion to combine the references, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine,* 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones,* 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

53. Furthermore, the Examiner recognizes that references cannot be arbitrarily altered or modified and that there must be some reason why one skilled in the art would be motivated to make the proposed modifications. Although the motivation or suggestion to make modifications must be articulated, it is respectfully submitted that there is no requirement that the motivation to make modifications must be expressly articulated within the references themselves. References are evaluated by what they suggest to one versed in the art, rather than by their specific disclosures, *In re Bozek,* 163 USPQ 545 (CCPA 1969).

54. The Examiner is concerned that the Applicant apparently ignores the mandate of the numerous court decisions supporting the position given above. The issue of obviousness is not determined by what the references expressly state but by what they would reasonably suggest to one of ordinary skill in the art, as supported by decisions in *In re Delisle* 406 Fed 1326, 160 USPQ 806; *In re Kell, Terry and Davies* 208 USPQ 871; and *In re Fine,* 837 F.2d 1071, 1074, 5 USPQ 2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu,* 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). Further, it was determined in *In re Lamberti* et al 192 USPQ 278 (CCPA) that:

(i) obvious does not require absolute predictability;

(ii) non-preferred embodiments of prior art must also be considered; and

(iii) the question is not express teaching of references but what they would suggest.

55. According to *In re Jacoby,* 135 USPQ 317 (CCPA 1962), the skilled artisan is presumed to know something more about the art than only what is disclosed in the applied references. Within *In re Bode,* 193 USPQ 12 (CCPA 1977), every reference relies to some extent on knowledge of persons skilled in the art to complement that which is disclosed therein. In *In re Conrad* 169 USPQ 170 (CCPA), obviousness is not based on express suggestion, but what references taken collectively would suggest.

56. In the instant case, the Examiner respectfully notes that each and every motivation to combine the applied references is accompanied by select portions of the respective references which specifically support that particular motivation. As such, it is NOT seen that the Examiner's combination of references is unsupported by the applied prior art of record. Rather, it is respectfully submitted that explanation based on the logic and scientific reasoning of one ordinarily skilled in the art at the time of the invention that support a holding of obviousness has been adequately provided by the motivations and

reasons indicated by the Examiner, *Ex pane Levengood* 28 USPQ 2d 1300 (Bd. Pat. App. & Inter., 4/22/93).

57. With regards to applicant's argument that Moore's code validation and applicant's code activation are different concepts, Examiner respectfully disagrees. First of all, it is noted that the features upon which applicant relies in the argument (i.e., goods authenticated at any number of checkpoints vs. authenticated at one destination *and* a known intended recipient and route) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Additionally, Moore, in at least abstract and column 4, line 32 - column 9, line 17, discloses several ways an activated code is verified to be authentic, just as applicant has claimed. Therefore, Moore's code validation and applicant's code activation are analogous concepts.

58. With regards to applicant's argument that Michael/Cunningham/Moore does not teach the concept of flagging a code as expired in response to successful verification of authentication code, Examiner respectfully disagrees. As pointed out in the previous office action, Cunningham, in least column 3, line 54 – column 4, line 3, discloses product media are given a number of validations which expire once the validations are exhausted or the product media are unique for each pharmaceutical used and would expire with the prescription of each unique product which would mean that the codes connected to the media are flagged as expired so they could not be used again. Therefore, Michael/Cunningham/Moore provides for flagging a code as expired in response to successful verification of authentication code.

Official Notice Not Traversed

59. In response to Applicant's non-traversal with respect to Examiner's taking of Official Notice, the limitations which were Officially Noticed in the previous office action are hereinafter deemed admitted prior art. The Examiner would like to note the requirements for traversing official notice from MPEP § 2144.03:

> To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111(b). See also *Chevenard, 139 F.2d at 713, 60 USPQ at 241* ("[I]n the absence of any demand by appellant for the examiner to produce authority for his statement, we will not consider this contention."). A general allegation that the claims define a patentable invention without any reference to the examiner's assertion of official notice would be inadequate. If applicant adequately traverses the examiner's assertion of official notice, the examiner must provide documentary evidence in the next Office action if the rejection is to be maintained. See 37 CFR 1.104(c)(2). See also *Zurko, 258 F.3d at 1386, 59 USPQ2d at 1697* ("[T]he Board [or examiner] must point to some concrete evidence in the record in support of these findings" to satisfy the substantial evidence test). If the examiner is relying on personal knowledge to support the finding of what is known in the art, the examiner must provide an affidavit or declaration setting forth specific factual statements and explanation to support the finding. See 37 CFR 1.104(d)(2). If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate. If the traverse was inadequate, the examiner should include an explanation as to why it was inadequate. (MPEP § 2144.03(C))

60. To adequately traverse such a finding, an applicant must specifically point out the supposed errors in the examiner's action, which would include stating why the noticed fact is not considered to be common knowledge or well-known in the art. See 37 CFR 1.111 (b).

61. If applicant does not traverse the examiner's assertion of official notice or applicant's traverse is not adequate, the examiner should clearly indicate in the next Office action that the common knowledge or well-known in the art statement is taken to be admitted prior art because applicant either failed to traverse the examiner's assertion of official notice or that the traverse was inadequate [emphasis added].

62. Because Applicant has not specifically pointed out any errors in the Examiner's action, the officially noticed facts in the 03/05/2009 office action are deemed admitted prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **JOSEPH BURGESS** whose telephone number is **(571)270-5547.** The Examiner can normally be reached on Monday-Friday, 9:00am-5:00pm. If attempts to reach the examiner by telephone

are unsuccessful, the Examiner's supervisor, **CHRISTOPHER GILLIGAN** can be reached at **(571)272-6770**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://portal.uspto.gov/external/portal/pair . Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **(866)217-9197** (toll-free).

Any response to this action should be mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

or faxed to **571-273-8300**. Hand delivered responses should be brought to the **United States Patent and Trademark Office Customer Service Window**:

Randolph Building

401 Dulany Street

Alexandria, VA 22314.

JOSEPH BURGESS

11/12/2009

Examiner

Art Unit 3626

/C. Luke Gilligan/

Supervisory Patent Examiner, Art Unit 3626